

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
1 August 2002 (01.08.2002)

PCT

(10) International Publication Number
WO 02/058575 A1

(51) International Patent Classification⁷: **A61B 17/72**

(21) International Application Number: **PCT/GB02/00311**

(22) International Filing Date: 25 January 2002 (25.01.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0102141.9 27 January 2001 (27.01.2001) GB

(71) Applicant and

(72) Inventor: **DAVIES, John, Bruce, Clayfield** [GB/GB]; 1 Mansfield Court, Livingston Village, West Lothian EH54 7BJ (GB).

(74) Agents: **MCCALLUM, William, Potter** et al.; Cruikshank & Fairweather, 19 Royal Exchange Square, Glasgow G1 3AE (GB).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

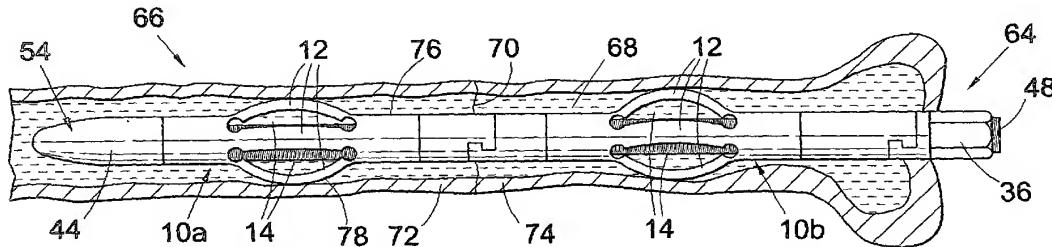
Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



(54) Title: IMPROVEMENTS IN OR RELATING TO EXPANDABLE BONE NAILS



WO 02/058575 A1

(57) Abstract: The present invention relates to bone nails for positioning fractured bone portions relative to one another. In particular, the present invention provides a bone portion securing device (60) adapted to be received within a bone cavity, the device including at least one portion (10) capable of being radially expanded under an applied force, the at least one expansion portion (10) having at least one portion (12), at least one characteristic of which is selected to be different to a corresponding at least one characteristic of at least one other part of the portion (12).

- 1 -

IMPROVEMENTS IN OR RELATING TO EXPANDABLE BONE NAILS

The present invention relates to bone nails for positioning fractured bone portions relative to one another, and in particular, though not exclusively, to 5 bone nails including expandable sections to laterally engage a cavity of each bone portion.

It is known that fractured bone portions can be united by the insertion of one or more bone nails (often known as intramedullary bone portion securing devices) 10 which remain in place until the fracture is healed, and then are preferably removed though they may alternatively be renewed replaced or remain in-situ if required. Current bone nails typically have diameter selected to provide sufficient strength to the nail while remaining narrow 15 enough to seek to limit the size of the aperture through which the bone nail is inserted; in other words the amount of bone or diameter of marrow canal which has to be removed to insert the nail. Once in position one or more sections of the nail expand to increase the diameter of 20 the nail over each relevant section. The expanded section(s) laterally engage the wall of the bone cavity (marrow canal) to fix the nail in position. Before the nail is removed the expanded section(s) are retracted to their original diameter to aid extraction.

25 Intramedullary devices as referred to above may

- 2 -

conveniently be used in the setting of bone fractures, being particularly useful in the case of long bones for example, a femur, humerus, radius or ulna. Such sites entail difficulties where the bone is required to be held
5 in place, since these bones are usually surrounded by a considerable thickness of muscle, which spaces a rigid support of plaster of Paris from the bone by a distance which is too great to ensure that the bone is accurately aligned and firmly held. Moreover, when the arm or leg is
10 in use, there may be rotary movement of the limb which could result in relative rotary movement between sleeve portions of the device.

Further, it is not uncommon for there to be more than one site of fracture in a bone, and particularly a long
15 bone. Moreover, the fracture may involve splintering or fragmentation of the bone such that the overall length may be difficult to maintain whilst the bone is healing, resulting in a shortened limb.

An example of a bone nail is disclosed in US Patent
20 No 4,453,539 to Raftopoulos et al entitled "An expandable intramedullary nail for the fixation of bone fractures". At one end of a sleeve are arranged a plurality of circumferentially spaced rectangular (or circular) openings. On rotating a screw thread along the bore of the
25 sleeve, rectangular (or spherical) elements protrude

- 3 -

through the sleeve to engage the bone cavity. In order to deploy the elements, an arrangement of spring clips, camming members and a pin is required. The number of parts which must be assembled to make this bone nail results in 5 a device which is complex to construct, and hence may suffer from mechanical failure where segments fail to deploy or worse, cannot be retracted for extraction of the bone nail.

An improved bone nail is that disclosed in UK Patent 10 No 2,268,068 to the present Applicant entitled "Devices having expansion means for securing end portions of tubular members" the content of which is included herein by reference. The disclosed device is suitable for use with a fracture of long bones, such as the humerus, femur, 15 radius or ulna, and comprises a rod adapted to be received within an elongate cavity of the bone. The nail is provided with at least two expansion sections mounted in tandem to grip wall portions of the cavity at two locations, one on each side of the fracture site. The 20 sections each provide a plurality of substantially rectangular slits formed in a sleeve surrounding the rod. An end surface of the sleeve abuts a flange on the rod. Tightening a nut on the rod therefore causes the slits to distort, i.e. supposedly expand outwardly. Additionally 25 the sleeve is in the form of a number of sleeve portions

- 4 -

. which are secured together by lugs and receiving slots in each portion so as to avoid relative rotational movement between the sleeve portions and between these and the rod.

This device has an advantage that it has a simple construction. However it also has a number of disadvantages. For example, the distortion of the slits is not controlled so the expanding portions may collapse inwards rather than expanding outwards on tightening. Further, on release the sleeve portions can become disengaged from one another as the compression force is removed causing retraction and removal to fail.

. It is an object of at least one embodiment of the present invention to obviate or mitigate at least one of the aforementioned disadvantages of the prior art.

15 According to a first aspect of the present invention, there is provided a bone portion securing device adapted to be received within a bone cavity, the device including at least one portion capable of being radially expanded under an applied force, the at least one expansion portion having at least one portion, at least one characteristic of which is selected to be different to a corresponding at least one characteristic of at least one other part of the portion.

Such selection is beneficial in ensuring that the 25 expansion portion is properly deployed, in use.

- 5 -

The at least one characteristic may comprise the thickness and/or width of the at least one part and the at least one other part.

The expansion portion may comprise at least one
5 elongate portion having a pair of elongate slots on either side thereof.

The at least one portion may comprise a first end of the at least one elongate portion, and preferably also comprise a second end of at least one elongate portion. In
10 such instance, the at least one other part may comprise a mid portion of the elongate portion, preferably forming a remainder of the elongate portion.

The first end and/or second end of the elongate portion may be thinner than and/or narrower than an
15 adjacent portion of the at least one elongate portion.

The at least one portion may comprise or further comprise a first end of at least one slot, and preferably also comprise a second end of at least one slot. In such instance, the at least one other part may comprise a mid
20 portion of the slot forming a remainder of the slot.

The first end and/or the second end of at least one slot may be broader than an adjacent portion of the at least one slot.

According to a second aspect of the present
25 invention, there is provided a bone securing device

- 6 -

adapted to be received within a bone cavity, the device including at least one portion capable of being radially expanded under an applied force, wherein the at least one expansion portion is shaped to elastically bow outwards 5 when a compressive force is applied axially to the expansion member.

According to a third aspect of the present invention, there is provided a bone securing device adapted to be received within a bone cavity, the device including at 10 least one portion capable of being radially expanded under an applied force, wherein the at least one expansion portion comprises at least one longitudinal portion fixed at either end to means which engage a compression coupling, wherein the profile of the at least one 15 longitudinal portion is narrowed at one or both ends of the at least one longitudinal portion.

Preferably, there are provided a plurality of longitudinal portions substantially equidistant spaced around a circumference of the expansion module.

20 Preferably, there are provided a plurality of expansion portions.

Preferably, the longitudinal portion has a stepped or curved profile.

Additionally, the outer surface of the longitudinal 25 portion may be serrated to provide grip with the inner

- 7 -

surface of a bone.

According to a fourth aspect of the present invention there is provided a bone portion securing device adapted to be received within a bone cavity, the device including at least one portion capable of being radially expanded under an applied force, wherein the at least one expansion portion includes at least one slot, the slot having at least one portion having a width greater than a width of a remainder of the at least one slot.

Preferably the at least one portion and the remainder of the slot are longitudinally displaced.

Preferably there are provided a plurality of expansion portions.

Preferably the/each expansion portion includes a plurality of elongate slots.

Preferably the at least one wider portion is provided at or near an end of the/each slot.

Advantageously the/each slot includes a first and second wider portions at first and second ends of the slot.

Preferably the remainder of the slot is substantially of a uniform width.

Preferably the remainder of the slot includes a first and second substantially parallel edges.

Preferably the wider portion(s) is/are at least part

- 8 -

circular in an elongate plane of the slot.

According to one embodiment of the present invention the device comprises;

at least two expansion modules, said expansion
5 module(s) being of substantially cylindrical unitary construction including a plurality of substantially longitudinal portions which, in use, are substantially lateral to a bone wall and which bow elastically outward when a compressive force is applied axially to the
10 expansion module;

at least one compression coupling, said compression coupling including compressive attachment means to engage the expansion module(s) in a fixed position with respect to the compression coupling and being capable of
15 transferring a compressive force; and

at least one compression means, said compression means being arranged to transfer a force, such as a rotational force, applied to at least one portion of a surface of the compression means to a compressive force
20 applied to the at least one compression coupling.

Preferably the plurality of longitudinal portions are substantially equidistantly spaced around a circumference of the expansion module(s).

Preferably adjacent longitudinal portions are
25 separated from each other by an elongate slot (expansion

- 9 -

apertures).

Additionally the/each elongate slot may have chamfered edges.

In longitudinal cross-section the/each slot may have
5 one end substantially broader than the oppositely opposed end. Alternatively one or both ends may be rounded.

More preferably the cross-section of the/each lead slot is dumb-bell shaped having circular end portions and a rectangular mid section. In a preferred embodiment the
10 end portions have a diameter which is substantially twice the width of the rectangular mid section.

The dumb-bell shape of the expansion aperture seeks to ensure that when a compressive force is applied to one or both ends of the slot in the longitudinal direction,
15 the longitudinal portion(s) will bow outwards from the expansion module.

The longitudinal portions may also be shaped to encourage them to bow elastically outward when the compressive force is applied. The shape may provide at
20 least one narrowed mid section. The mid section may comprise a substantially central section radially thinner than the end sections of the respective longitudinal portion. Alternatively, the longitudinal portions may be loaded by having a stepped or curved surface profile.

25 Preferably the compressive attachment means of the

- 10 -

compression coupling is in the form of a ratchet. More preferably the ratchet is self locking. The compressive attachment means may engage barbs on an external surface of the expansion module(s). Preferably also the attachment means includes at least two anti-rotation grooves. The anti-rotation grooves engage a portion of an expansion module such that the expansion module cannot rotate with respect to the compression coupling. Additionally, anti-rotation grooves may be included in the expansion module.

In a preferred embodiment the combination of a self locking ratchet together with anti-rotation grooves ensures that the components of the device remain attached to each other when the nail is extracted.

Preferably the device also comprises a central connector or rod. The central connector may be a tie bar.

The expansion modules and the compression couplings may be mounted alternately onto the central connector to make up the required length of the device. Compression couplings of varying lengths can be used to allow for a desired separation between expansion modules.

The central connector may comprise a screw-threaded surface for engaging the components of the device. Alternatively the central connector may include one or more surfaces to engage at least a portion of a component mounted thereon.

- 11 -

Preferably the device also comprises a nose cone, positioned at a the front of the central connector or at a first expansion module, the compression means preferably being attached at a rear of the central connector or at a 5 final compression coupling.

Preferably the nose cone has a rounded front face to provide for ease of insertion of the device into a bone cavity.

The nose cone may be attached to the central 10 connector.

Alternatively the nose cone may be formed integrally with the central connector. Further the nose cone may include a sleeve.

Preferably also the nose cone may include rigid 15 attachment means to engage a first expansion module in a fixed position with respect to the nose cone and consequently the central connector. Preferably the rigid attachment means is in the form of a ratchet. More preferably the ratchet is self locking. The rigid 20 attachment may engage barbs on the external surface of the first expansion module.

The compressive attachment means and the rigid attachment means differ in that the compressive attachment means provides attachment between an expansion module and 25 a compression coupling which, together transmit a

- 12 -

compressive force. In contrast the rigid attachment means provides attachment between a nose cone and the first expansion module which, when a compressive force is applied to the first expansion module via the compressive 5 means intermediary expansion module(s) and compression coupling(s), the first expansion module bears against a surface of the nose cone or a surface of the sleeve which applies the required compressive force for the longitudinal position(s) of the expansion module(s) to bow 10 elastically outward.

Preferably the expansion module is made of a stiffly resilient plastics material. In a preferred embodiment the expansion module is made at least partly of, and preferably substantially of, titanium or optionally of a 15 titanium alloy. Alternatively, the expansion module is made of ultra-high molecular weight polyethylene (UHMWPE). The compression coupling and the compression means may be made of a metal or metal alloy. In a preferred embodiment the compression coupling and the compression means are 20 made of titanium alloy e.g. TiAl₆V₄.

According to a further aspect of the present invention, there is provided an expansion module for use as a portion of a bone portion securing device adapted to be received within a bone cavity, the module including at 25 least one portion capable of being radially expanded under

- 13 -

an applied force, the at least one expansion portion having at least one portion, at least one characteristic of which is selected to be different to a corresponding at least one characteristic of at least one other portion of
5 the portion.

According to a yet further aspect of the present invention there is provided an expansion module for use as a portion of a bone portion securing device adapted to be received within a bone cavity, the module being capable of
10 being radially expanded under an applied force, wherein the at least one expansion portion includes at least one slot the slot having at least one portion having a width greater than a width of a remainder of the at least one slot.

15 According to one preferred embodiment of the present invention the expansion module is of substantially cylindrical unitary construction and includes a plurality of substantially longitudinal portions which, in use, are substantially lateral to the bone wall which bow
20 elastically outward when a compressive force is applied.

Preferably the expansion module includes coupling means for coupling the expansion module to other components of a bone portion securing device. Preferably the coupling means comprise barbs positioned on a surface
25 of the expansion module such that the barbs engage in a

- 14 -

ratchet fashion when forced against a surface of another component. The coupling means may be self locking.

More preferably the coupling means includes a portion of the expansion module which engages a portion of another 5 component such that the expansion module and the component are held in a fixed relationship and cannot rotate with respect to each other. The portion of the expansion device may be one or more anti-rotation grooves where the component may comprise engaging lugs to the grooves or 10 complimentary anti-rotation grooves.

Preferably the expansion module is made from a stiffly resilient plastics material such that it can elastically bow under a compressive force and return to its original shape when the compressive force is removed.

15 In an embodiment the expansion module is made of titanium. In a further embodiment the expansion module is made from a polymer of low calcium stearate superpressed UHMWPE, with a tensile stress of 700N/mm² and a creep (over 1000 hours) of 230/250Nmm².

20 According to a yet further aspect of the present invention there is provided a bone portion securing device comprising a plurality of parts adjacent ends of adjacent parts including one-way interengaging locking means adapted to allow engagement of the adjacent ends but to 25 prevent disengagement thereof.

- 15 -

Preferably, the locking means comprise ratchet means formed on the adjacent ends.

Preferably the locking means engage one another by relative movement of the adjacent ends together.

5 Preferably the ratchet means comprise first and second toothed or barbed surfaces formed on an inner facing surface(s) of a first part and an outer facing surface(s) of a second part.

10 Advantageously the surfaces each provide a plurality of teeth or barbs.

Advantageously the surfaces are substantially planar and may be substantially parallel to a long axis of the part upon which it is formed.

15 Preferably there are further provided means for preventing relative rotation of the adjacent parts when assembled together.

The means to prevent relative rotation may comprise interengaging grooves and lugs carried on each of the adjacent parts.

20 An embodiment of the present invention will now be described by way of example with reference to the accompanying drawings in which:

Figures 1 (a), (b) and (c) show a side view, an end view and a side view to an enlarged scale of an expansion 25 module for use in a bone portion securing device according

- 16 -

to an embodiment of the present invention;

Figures 2 (a) to (e) show profiles of longitudinal portions of an expansion module according to embodiments of the present invention;

5 Figures 3 (a) to (e) show a side, a further side view, a front view, an end view and a side view to an enlarged scale of a compression coupling for use in a bone portion securing device according to the present invention;

10 Figures 4 (a) to (c) show a side view, a further side view and an end view of a compression nut for use in a bone portion securing device according to the present invention;

15 Figures 5 (a) and (b) show a cross-sectional perspective view and a cross-sectional view of a nose cone for use in a bone portion securing device according to the present invention;

20 Figures 6(a) and (b) show a perspective view and a side view of a first end (front) portion of a bone portion securing device according to the present invention;

Figures 7 (a) and (b) show a perspective view and a side view of a second end portion of a bone portion securing device according to the present invention;

25 Figure 8 shows a partial fragmentary perspective diagrammatic representation of a view of a bone portion

- 17 -

securing device according to the present invention;

Figure 9 shows a schematic side view of a bone portion securing device according to the present invention, in use, within a bone cavity (drawn in cross-section for clarity);

Figure 10 shows (a) side views of an expansion module for use in a bone portion securing device according to a further embodiment of the present invention; and (b) a profile of a longitudinal portion of an expansion module according to the embodiments of the present invention;

Figures 11(a) and (b) are a series of views of a yet further embodiment of an expansion module; and

Figures 12(a) and (b) are schematic representations of a bone nail according to a further embodiment of the present invention employing the expansion module of Figure 10.

Reference is first made to Figure 1(a) of the drawings which depicts an embodiment of the present invention comprising expansion module, generally indicated by reference numeral 10. Expansion module 10 is fashioned from a single piece of tubular material, e.g. titanium. The material is selected so that it will bow under an applied compressive force without splitting, crushing or deforming. Arranged circumferentially around the expansion module 10 are six longitudinal portions 12 spaced equally

- 18 -

apart. Between each longitudinal portion 12 is a slot in the form of an expansion aperture 14. Each expansion aperture 14 has a generally dumb-bell shape provided by forming, e.g. drilling two circular apertures 16 a, 16 b 5 and a connecting rectangular aperture 18. The edges of the expansion apertures 14 are chamfered and the expansion apertures are drilled through the entire thickness of the wall of the expansion module 10. At each end 28a, 28b of the expansion module 10 as best illustrated in Figure 1 10 (c), are provided locking means comprising a set of external locking barbs 20. The barbs 20 are formed by removing an angular section of material circumferentially from the surface of the expansion module 10. Alternatively the barbs 20 could be cast or moulded with or onto the 15 module 10. The barbs 20 are of uniform heights. In addition two small sections of each barb 20 are removed in the longitudinal direction of the expansion module 10. These small sections are formed at directly opposite sides 20 of the expansion module 10 to form anti-rotation grooves 22a, b as shown in Figure 1 (b). The purpose of the apertures 16 a, b, barbs 20 and anti-rotation grooves 22a, b will be described hereinafter.

Each longitudinal portion 12 in Figure 1 is shaped to match the dumb-bell shape of the expansion apertures 14. 25 Figures 2 (a) to (e) show alternative embodiments of

- 19 -

longitudinal portion 12 which are loaded to ensure successful outward bowing of the longitudinal portions 12 when a force is applied. Figure 2(a) shows in radial profile a longitudinal portion 12a for an expansion module. A narrow central section 110 is weaker than wider end sections 112a, 112b so that when a compressive force is applied to ends 114a, 114b the longitudinal portion 12a will bow outwards in the direction of the arrow A causing the narrow section 110 to engage with bone.

10 The arrangement shown in Figure 2 (b) will provide an enhanced outward bowing effect of the longitudinal portion 12b as the central section 110 is now partly bowed when the expansion module is inserted into the bone.

Figure 2(c) shows a longitudinal portion 12c again in radial profile along the longitudinal axis of the expansion module. An inner surface 116 is stepped to provide indented portions 116a-d. This weakened inner surface will deform on compression of the ends 114a,b causing the longitudinal portion 12c to expand outwards in the direction of arrow A. In Figure 2(d) both surfaces have been stepped with indents 116a, b, c which are arranged to weaken the longitudinal portion 12d on compression causing expansion in the direction of arrow A.

25 Figure 2(e) shows a further embodiment of a longitudinal portion 12e viewed from above the edges of

- 20 -

the portion 12e are curved to provide two wide sections 118a,b and a narrow central section 110 as for Figure 2(a) and (b) on compression of the ends 114a,b. The central section 110 is pushed out of the page in the direction of
5 A.

Reference is now made to Figure 3 (a) of the drawings which depicts a compression coupling, generally indicated by reference numeral 24. A first end 26a provides a receiving ratchet of dimensions to engage an end 28a, 28b of an expansion module 10, as shown in Figure 3 (e). Inwardly opposed barbs 30 also include matching anti-rotation grooves 32a, 32b to the grooves 22a, 22b of the expansion module 10. The anti-rotation grooves 32a, 32b are shown in Figure 3 (c). At a second end 26b, figures 10 15 3(b) and 3(d) is a transverse slot 34. The slot 34 provides for the engagement of the coupling 24 to a compression nut.

In a further embodiment of the present invention the coupling 24 has substantially identical ends both as
20 described for the first end 26a above.

The coupling 24 may be constructed of TiAl₆, bio-compatible non-corrosive alloy, which is strong enough to transmit a compressive force. The length of the coupling
24 is dependent on the separation required between
25 expansion modules 10.

- 21 -

A coupling means comprising a nut 36 is illustrated in Figure 4. The nut 36 is conveniently made of the same material as the compression coupling 24. The nut 36 comprises a hex screw head 38 which can be turned by a 5 spanner or socket set, Internal to the nut 36 is a screw-threaded bore 40 which extends the length of the nut 36. One end 42 of the nut 40 is configured to mate with the transverse slot 34 of the compression coupling 24 described above.

10 A further component of an intermedullary bone nail is shown in Figure 5 and is generally referred to as a nose cone 44. A central tie bar 48 is a screw threaded rod running the length of the bone nail. An end section 46 of the bar 48 is threaded at a smaller size and fits into the 15 nose cone body 50 which is bored and tapped. On assembling the nose cone 44, the end section 46 is welded or otherwise fixed into the nose cone body 50 and a TIG welded chamber 52 is provided to give a rounded front face 54 to the nose cone 44. A circumferential portion 58 of the nose cone 44 is formed to receive an end 28 of an 20 expansion module by the same arrangement as described for the first end 26a of the compression coupling 24. At a front end of the circumferential portion 58 are surfaces which represent the compression face 56 for the bone nail.

25 The construction of an embodiment of an

- 22 -

intermedullary 25 bone portion securing device 61 will now be described making reference to Figures 6, 7 and 8.

A first expansion module 10a is inserted over the tie bar 48 and the barbs 20 at a first end 28a of the 5 expansion module 10a engage the circumferential portion 58 of the nose cone 44 in a self locking ratchet mechanism.

In addition complimentary anti-rotation grooves 32a, 32b interlock to prevent rotational movement of the expansion module 10a with respect to the nose cone 44. The 10 barbs 20 of the second end 28b of the expansion module 10a mate with a compression coupling 24 which is mounted on the tie bar 48. Mating is by the self locking ratchet mechanism 29 and anti-rotation grooves 32a, 32b described hereinbefore. A joint assembly of the front 60 of a bone 15 portion securing device 61 is shown in Figure 6.

Depending on the separation required between the two sets of longitudinal portions on adjacent expansion modules 10, one or more compression couplings 24 are mounted on the tie bar 48. Alternatively a single 20 compression coupling 24 of the desired length is used. Any number of expansion modules 10 may be mounted on the tie bar 48 and it is optional as to whether compression couplings 24 are inserted between each expansion module 10.

25 When the desired number of expansion modules 10 have

- 23 -

been inserted onto the tie bar 48 an end joint assembly 62 is constructed as shown in Figure 7. Once the final expansion module 10b is mounted on the tie bar 48 the bone nail 61 is completed with a final compression coupling 24a 5 and the compression nut 36. The end 42 of the compression nut 36 is slid into the transverse slot 34 of the compression coupling 24a. When engaged together the coupling 24a is mounted on the tie bar 48 and the nut 36 is screwed onto the end of the tie bar 48 to hold all 10 components of the bone nail 61 in place. The compressive coupling 24a is held to the final expansion module 10b by a self locking ratchet mechanism and anti-rotation grooves 32a, 32b as described before. An exploded view of a complete bone portion securing device 61 is illustrated in 15 Figure 8.

Reference is now made to Figure 9 of the drawings which illustrates an intermedullary bone portion securing device, generally indicated by reference numeral 10a, in use within a fractured bone generally indicated by 20 reference numeral 66. The bone 66 has been drawn in cross-section to allow for clarity of view of the device 10a. The device 10a is shown received in the narrow channel or cavity 68 of the bone 66, which in the present example is a mammalian humerus. The bone 66 is shown with a fracture 25 at 70 which requires bone portions 72 and 74 to be re-

- 24 -

united.

The surgeon or veterinary practitioner will have pre-drilled a bore 76 through the bone cavity 68 to receive the device 64. This bone will be drilled at the elbow.

5 With the compression nut 36 in an untightened position with all the components mounted on the tie bar 48, the device 61 is pushed into the bone 76. The front face 54 of the device 64 is rounded to reduce friction and aid insertion. The device 64 is positioned so that an
10 expansion module 10a, 10b lies on either side of the fracture 70. When the correct positioning is obtained the compression nut 36 is tightened using a spanner or socket wrench. On tightening the nut 36 the components are forced against each other towards the nose cone 44. The front end
15 28a of the first expansion module 10a bears against the compression face 56 of the nose cone 44 and applies a compression force. This is shown and described with reference to Figure 5. The force is transmitted through the components.

20 When each expansion module 10a, 10b is subjected to the axial compressive force, the expansion apertures 14 begin to widen and the longitudinal portions 12 bow outwards elastically. As the force is increased the length of each expansion module 10a, b decreases and the
25 effective diameter of each expansion module 10a, 10b

- 25 -

increases. The longitudinal portions 12 bow until they contact the bone cavity wall 76. The shape of the expansion apertures 14 ensure that the longitudinal portions 12 bow outwards from the tie bar 48 and central 5 axis of the device 64. Once expanded, the device 61 is held in position by the contact between the cavity wall 78 and the longitudinal portions 12. The expansion modules 10a, 10b remain expanded as long as the compression nut 36 remains tightened.

10 Once the fracture 70 has healed or if the device 61 requires to be removed, the compression nut 36 is loosened by reversing the above procedure. This releases the compressive force and the expansion modules 10a, 10b lengthen as the longitudinal portions 12 disengage from 15 the cavity wall 78 and return to their original positions. The device 61 is then extracted from the healed bone by pulling the device 61 from the bone 76. The incorporation of anti-rotation grooves and ratchet fittings between the components of the device 61 seeks to ensure that the 20 components do not become detached from the device 61 during the extraction process.

Figure 10(a) depicts a further embodiment of the present invention comprising expansion module 80. Arranged circumferentially around the expansion module 10c are 25 three longitudinal portions 82. Between each longitudinal

- 26 -

portion 82 is a slot in the form of an expansion aperture 84. Locking means 86 are provided at each end of the expansion module.

The longitudinal portions 82 are loaded to ensure 5 successful outward bowing of the portions when a force is applied. Figure 10(b) illustrates in detail such a longitudinal portion in profile. An inner and outer surface are curved to provide a weakened inner surface which will deform outwards on compression of the ends. A 10 serrated area 88 of the outer surface of the longitudinal portion 82 provides grip with the inner surface of the bone (not shown).

Figures 11(a) and (b) are a series of views of a yet further embodiment of an expansion module 90. In this 15 embodiment 90, the character that is varied is the thickness. End portions 94 of the strip 92 are broader as compared to the mid portions 96 of said strip 92.

Figures 12(a) and (b) are schematic representations 20 of a bone nail 100 according to a further embodiment of the present invention employing the expansion module 80 of Figure 10. The assembly of the bone nail 100 includes couplings 112 to couple together two expansion modules 80. The assembly also includes nose cone 114a in Figure 12(a) and a modified nose cone 114b in Figure 12(b).

25 A principal advantage of the present invention is

- 27 -

that it provides a modular self locking IC humeral nail. In particular the bone portion securing device is designed to be fail safe in that, under compression, an expansion module of the device will always expand outwards to 5 contact the cavity walls. In addition the device is designed so that it will not come apart when extracted from a bone.

It will be appreciated by one skilled in the art that various modifications may be made to the embodiments 10 described hereinbefore without departing from the scope of the invention.

In particular, it will be appreciated that there may well be gaps between bone edges at any of the fractures but this is in no way detrimental to the operation of the 15 securing device of the invention. Such gaps will in any case tend to fill in as the bone heals.

It will also be appreciated that the use of a device according to the invention may be controlled to an appreciable degree by the manner in which the apertures of 20 the expansion module is formed. The extent of the deformation brought about by the application of compressive force in a longitudinal direction can be controlled by selection from a number of variables, e.g. number of apertures in each annular group, thickness of 25 expansion module wall, choice of material for the

- 28 -

expansion module, width and/or length of apertures, width of position intervening between the apertures and so on. Moreover, the deformation characteristics of the expansion modules may be selected to vary between two or more area 5 of the bone, so that sequential expansion, sequentially arranged if desired, can be achieved.

It will also be understood that the cross-section of the expansion modules, longitudinal portions and couplings, although described as above as being 10 conveniently circular, may be oval, triangular or any convenient cross-section as desired.

In addition, as briefly referred to above, there is the facility now provided for adjustment of the device during the insertion thereof if required.

15 It is also possible to select the material of the expansion modules and couplings so that they are degradable in time and does not require to be removed once the bone has healed. The rod means may be withdrawn from the bone through the access point, e.g. the elbow, at 20 which actuation of the expansion devices was brought about.

- 29 -

CLAIMS

1. A bone portion securing device adapted to be received within a bone cavity, the device including at least one portion capable of being radially expanded under 5 an applied force, the at least one expansion portion having at least one portion, at least one characteristic of which is selected to be different to a corresponding at least one characteristic of at least one other portion of the portion.

10

2. A bone portion securing device according to claim 1, wherein the at least one characteristic comprises a thickness and/or width of the at least one part and the at least one other part.

15

3. A bone portion securing device according to claim 1, wherein the expansion portion comprises at least one elongate portion having a pair of elongate slots on either side thereof.

20

4. A bone portion securing device according to claim 1, wherein the at least one portion comprises a first end of the at least one elongate portion and a second end of at least one elongate portion.

25

- 30 -

5. A bone portion securing device according to claim 4, wherein the at least one other part comprises a mid portion of the elongate portion forming a remainder of the elongate portion.

5

6. A bone portion securing device according to claims 4 or 5, wherein the first end and/or second end of the elongate portion is thinner or thicker and/or narrower or broader than an adjacent portion of the at least one 10 elongate portion.

7. A bone portion securing device according to claim 1, wherein the at least one portion may comprise or further comprise a first end of at least one slot, and a 15 second end of at least one slot.

8. A bone portion securing device according to claim 7, wherein the at least one other part comprises a mid portion of the slot forming a remainder of the slot.

20

9. A bone portion securing device according to claim 1, wherein the first end and/or the second end of at least one slot is broader than an adjacent portion of the at least one slot.

25

- 31 -

10. A bone securing device adapted to be received within a bone cavity, the device including at least one portion capable of being radially expanded under an applied force, wherein the at least one expansion portion 5 is shaped to elastically bow outwards when a compressive force is applied axially to the expansion member.

11. A bone securing device adapted to be received within a bone cavity, the device including at least one portion capable of being radially expanded under an applied force, wherein the at least one expansion portion 10 comprises at least one longitudinal portion fixed at either end to means which engage a compression coupling, wherein the profile of the at least one longitudinal 15 portion is narrowed at one or both ends of the at least one longitudinal portion.

12. A bone portion securing device according to claim 11, wherein a plurality of longitudinal portions 20 substantially equidistant spaced around a circumference of the expansion module are provided.

13. A bone portion securing device according to claims 11 or 12, wherein the longitudinal portion has a 25 stepped or curved profile.

- 32 -

14. A bone portion securing device according to any one of claims 11 to 13, wherein the outer surface of the longitudinal portion is serrated to provide grip with the inner surface of a bone.

5

15. A bone portion securing device adapted to be received within a bone cavity, the device including at least one portion capable of being radially expanded under an applied force, wherein the at least one expansion 10 portion includes at least one slot, the slot having at least one portion having a width greater than a width of a remainder of the at least one slot.

16. A bone portion securing device according to 15 claim 15, wherein at least one portion and the remainder of the slot are longitudinally displaced.

17. A bone portion securing device according to claims 15 or 16, wherein the/each expansion portion 20 includes a plurality of elongate slots.

18. A bone portion securing device according to any one of claims 15 to 17, wherein the/each slot includes a first and second wider portions at first and second ends 25 of the slot.

- 33 -

19. A bone portion securing device according to
claim 18, wherein the remainder of the slot is
substantially of a uniform width.

5

20. A bone portion securing device comprising
at least two expansion modules, said expansion
module(s) being of substantially cylindrical unitary
construction including a plurality of substantially
10 longitudinal portions which, in use, are substantially
lateral to a bone wall and which bow elastically outward
when a compressive force is applied axially to the
expansion module;

at least one compression coupling, said compression
15 coupling including compressive attachment means to engage
the expansion module(s) in a fixed position with respect
to the compression coupling and being capable of
transferring a compressive force; and

20 at least one compression means, said compression
means being arranged to transfer a force, such as a
rotational force, applied to at least one portion of a
surface of the compression means to a compressive force
applied to the at least one compression coupling.

25 21. A bone portion securing device according to

- 34 -

claim 20, wherein the plurality of longitudinal portions are substantially equidistantly spaced around a circumference of the expansion module(s) and are separated from each other by an elongate slot (expansion apertures).

5

22. A bone portion securing device according to claims 20 or 21, wherein the/each elongate slot have chamfered edges.

10 23. A bone portion securing device according to any one of claims 20 to 22, wherein one or both ends of the/each slot are rounded in longitudinal cross-section.

15 24. A bone portion securing device according to any one of claims 20 to 22, wherein the longitudinal portions are loaded by having a stepped or curved surface profile.

20 25. A bone portion securing device according to claim 20, wherein the compressive attachment means of the compression coupling is in the form of a self-locking ratchet.

25 26. A bone portion securing device according to claim 20, wherein the attachment means includes at least two anti-rotation grooves which engage a portion of an

- 35 -

expansion module such that the expansion module cannot rotate with respect to the compression coupling.

27. A bone portion securing device according to any
5 one of claims 1, 10, 11, 15 or 20, wherein the expansion module is made of a stiffly resilient plastics material, titanium or titanium alloy.

28. An expansion module for use as a portion of a
10 bone portion securing device adapted to be received within a bone cavity, the module including at least one portion capable of being radially expanded under an applied force, the at least one expansion portion having at least one portion, at least one characteristic of which is selected
15 to be different to a corresponding at least one characteristic of at least one other portion of the portion.

29. A bone portion securing device substantially as
20 described in Figures 1 and 3 to 9, or in Figures 2a, 2b,
2c, 2d, 2e or 10.

30. An expansion module substantially as described
in Figures 1 or 9.

1/12

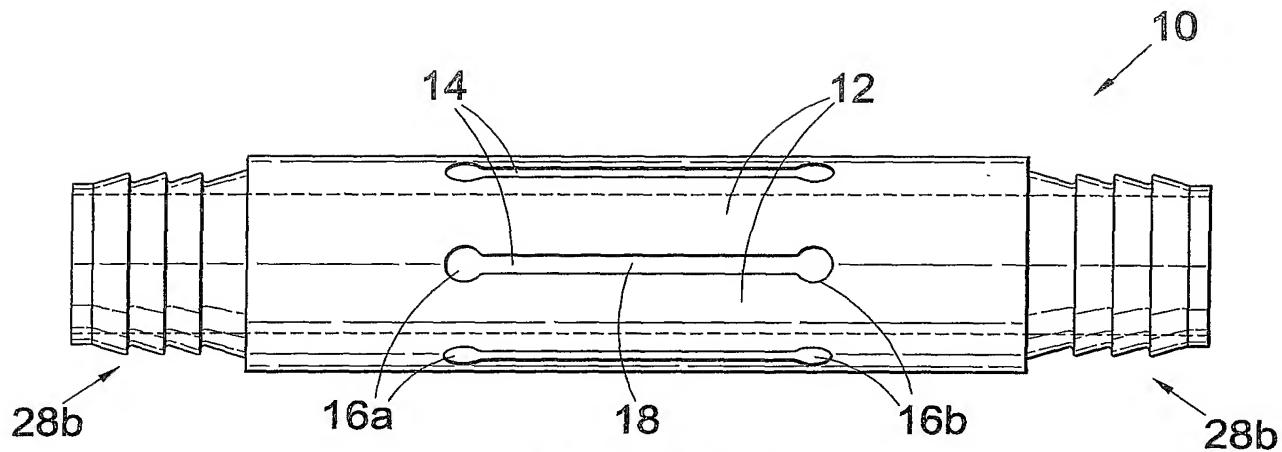


Fig. 1a

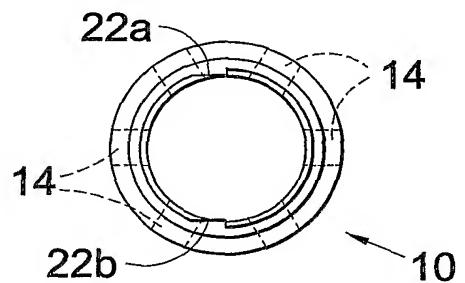
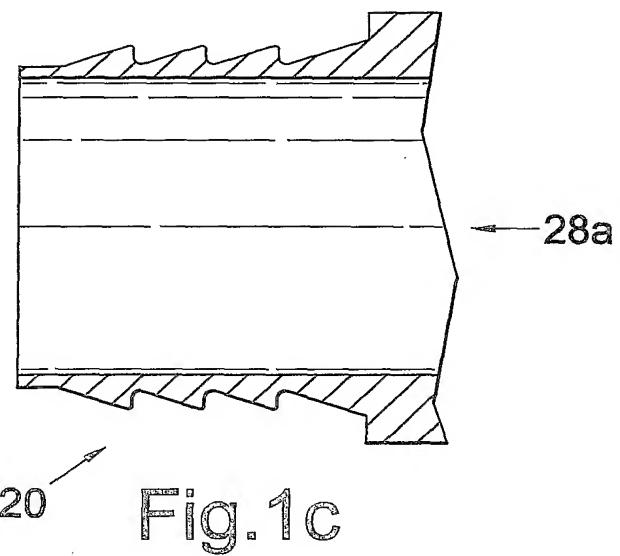
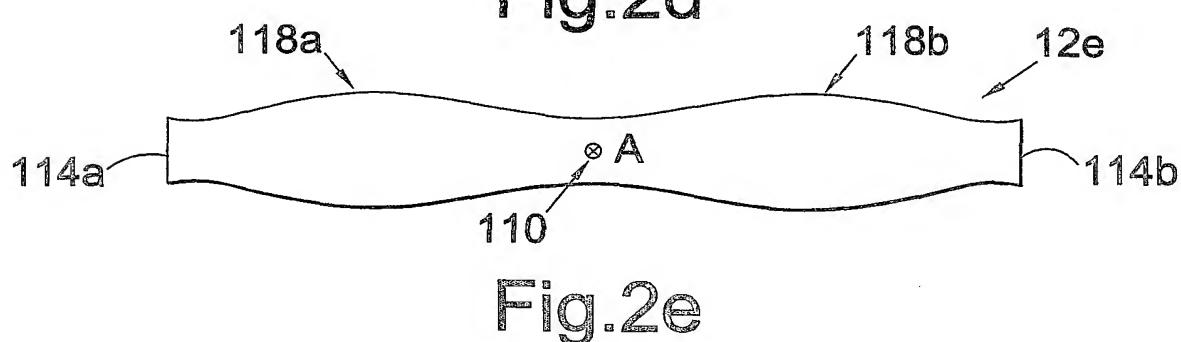
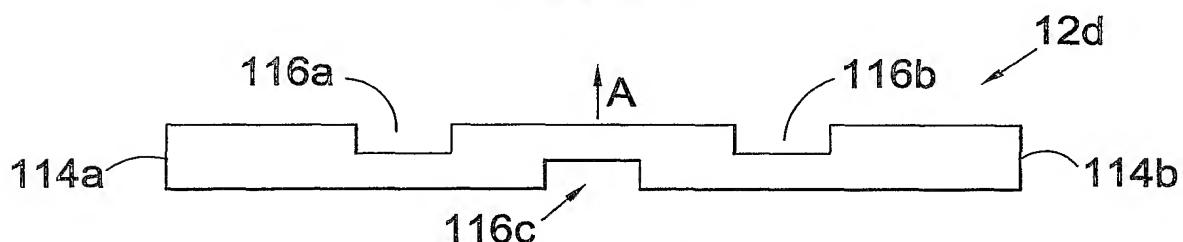
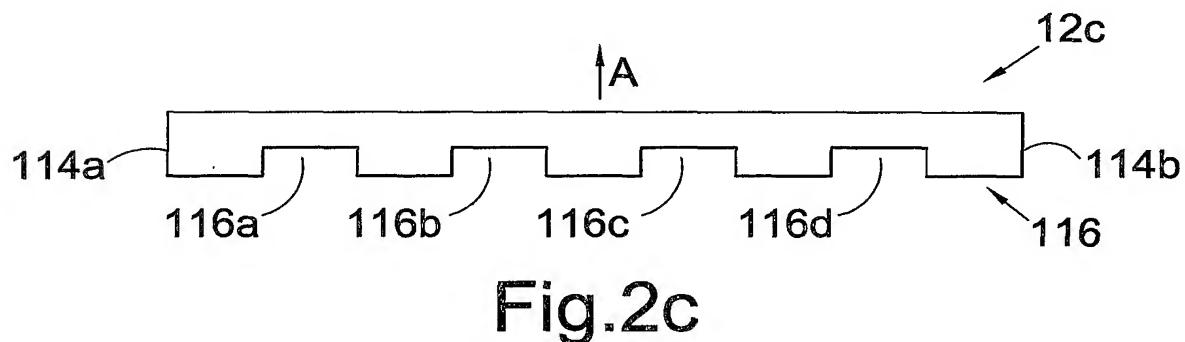
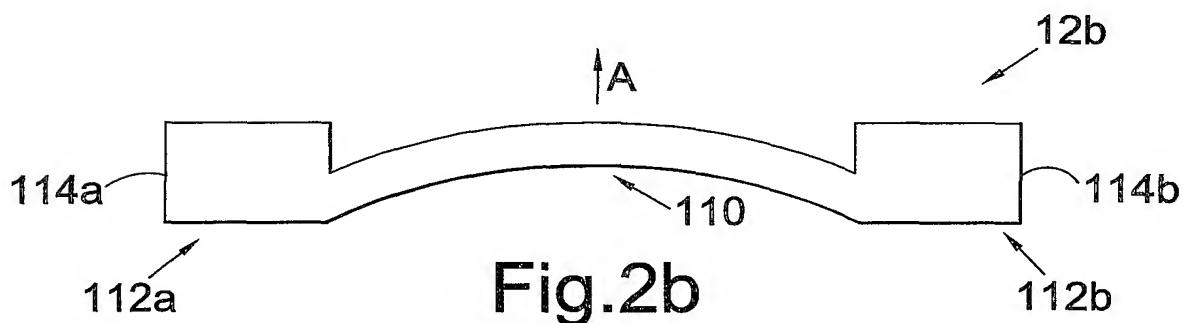
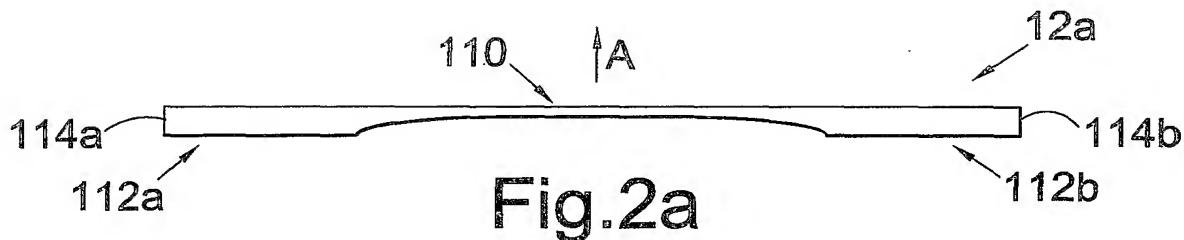


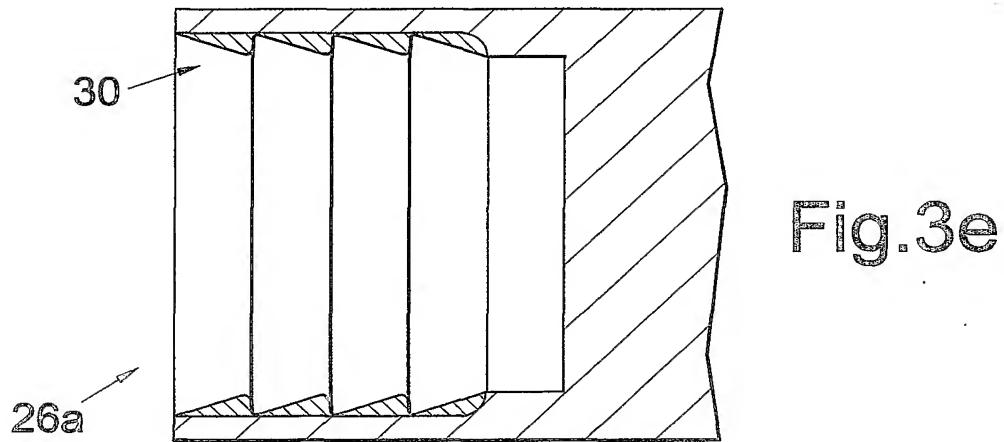
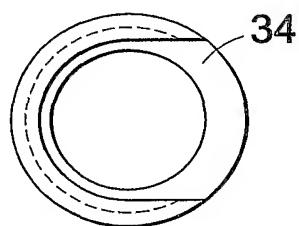
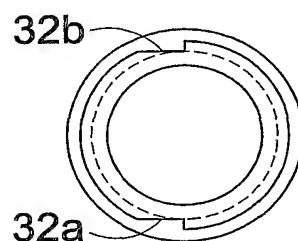
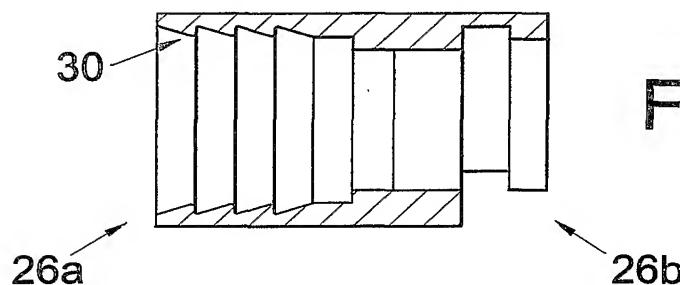
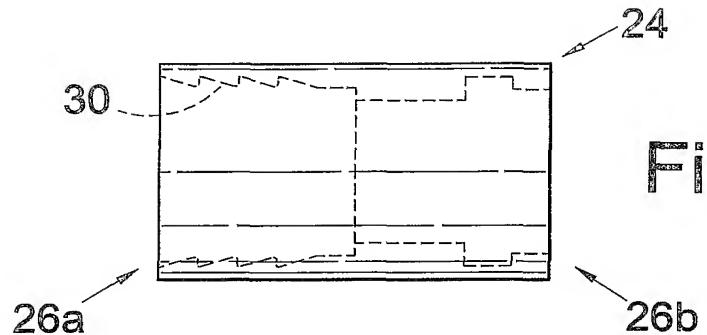
Fig. 1b



2/12



3/12



4/12

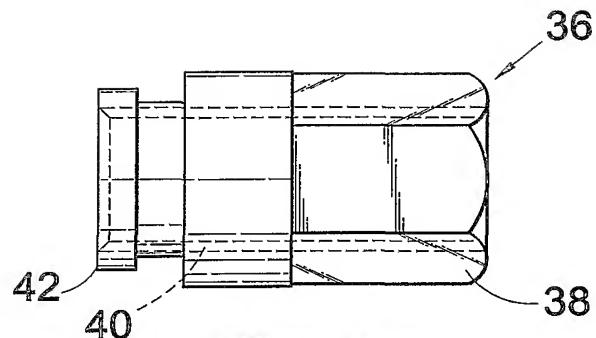


Fig.4a

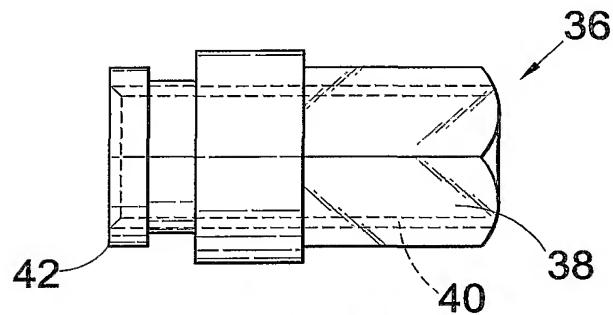


Fig.4b

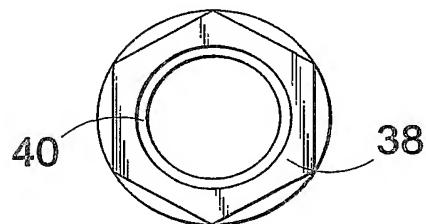


Fig.4c

5/12

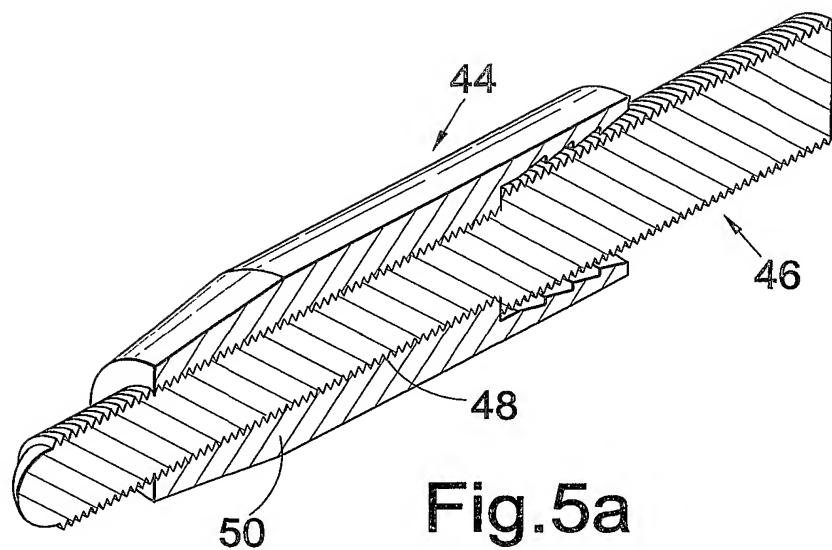


Fig. 5a

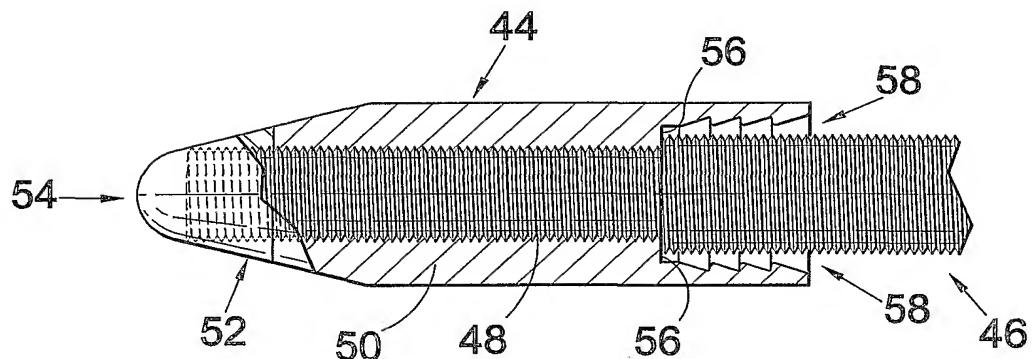
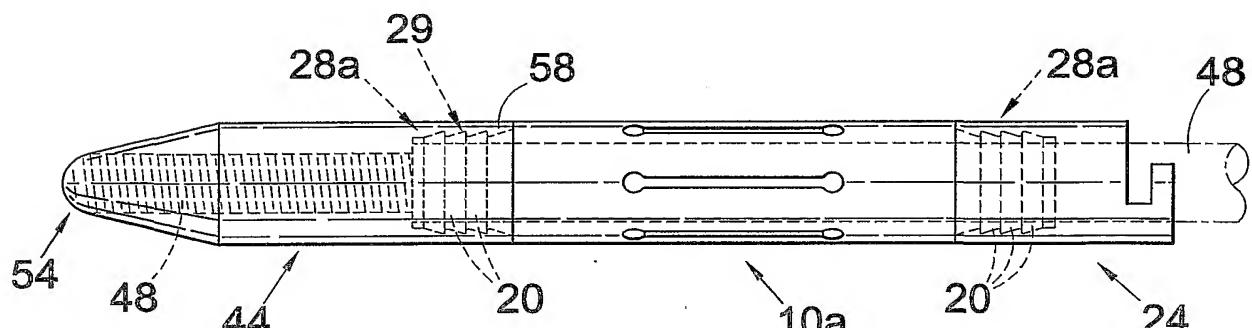
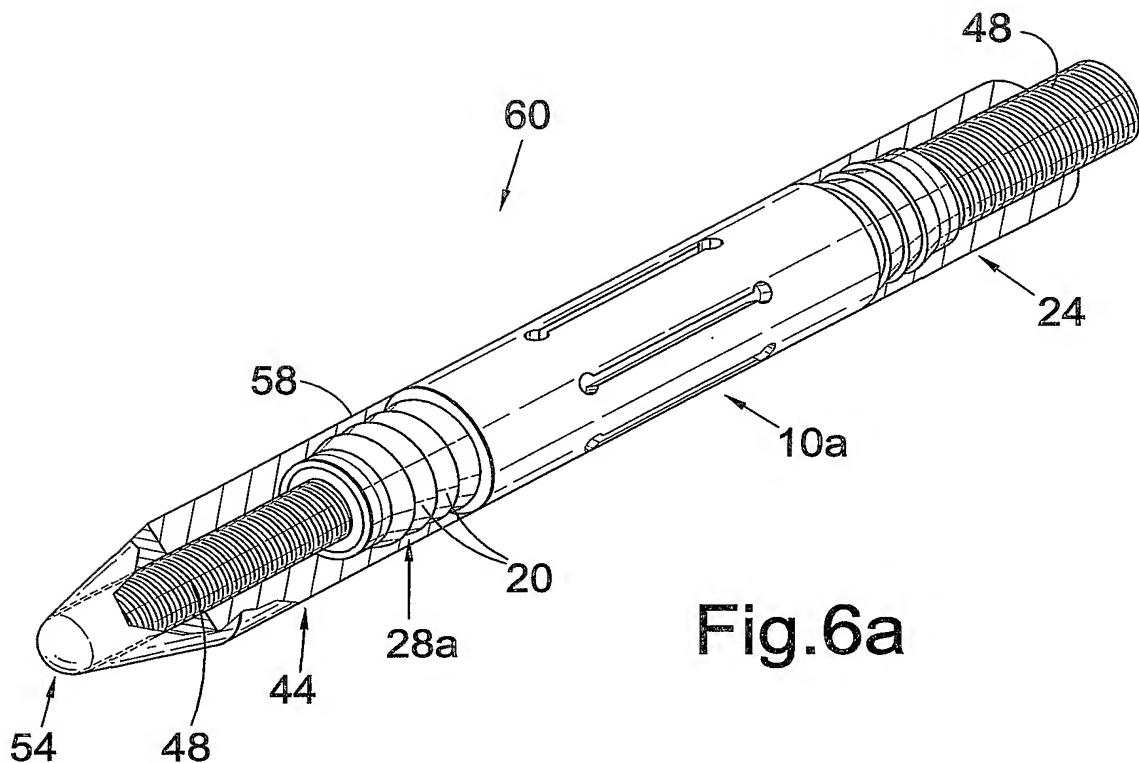


Fig. 5b

6/12



7/12

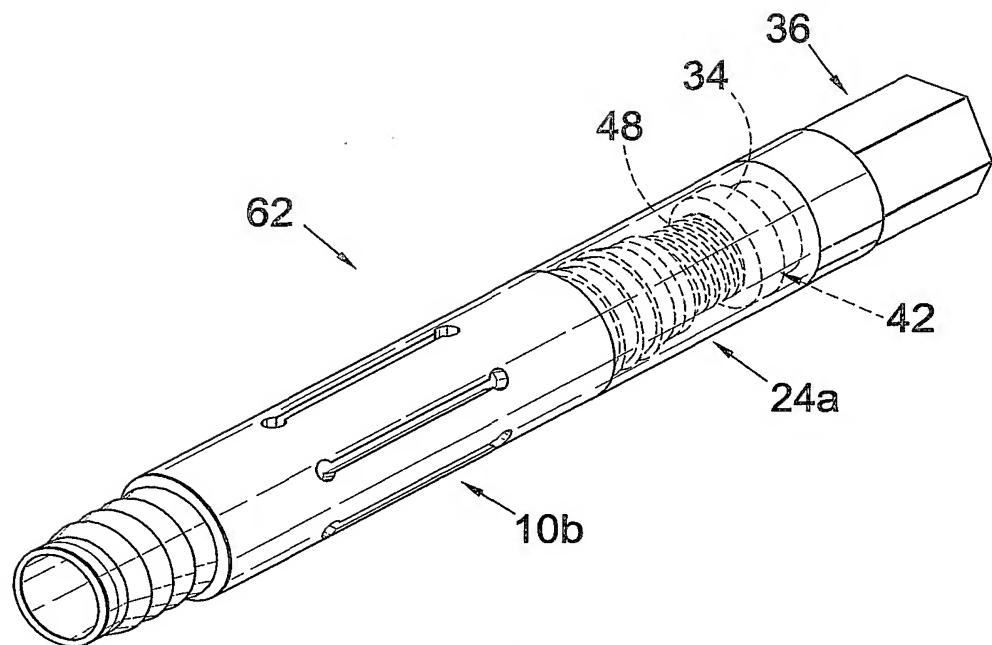


Fig.7a

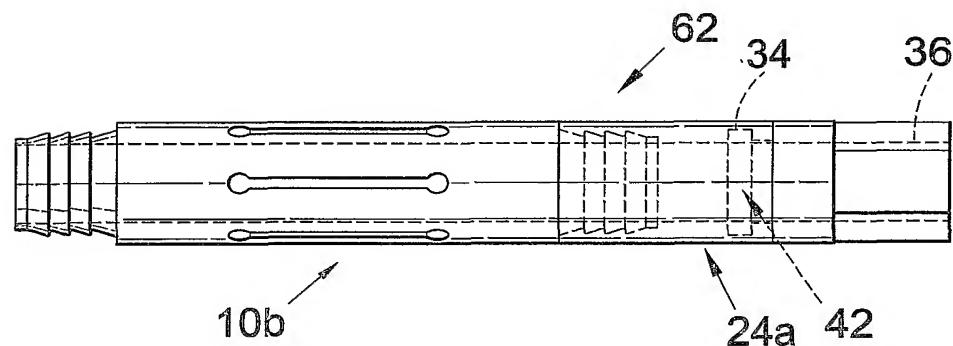
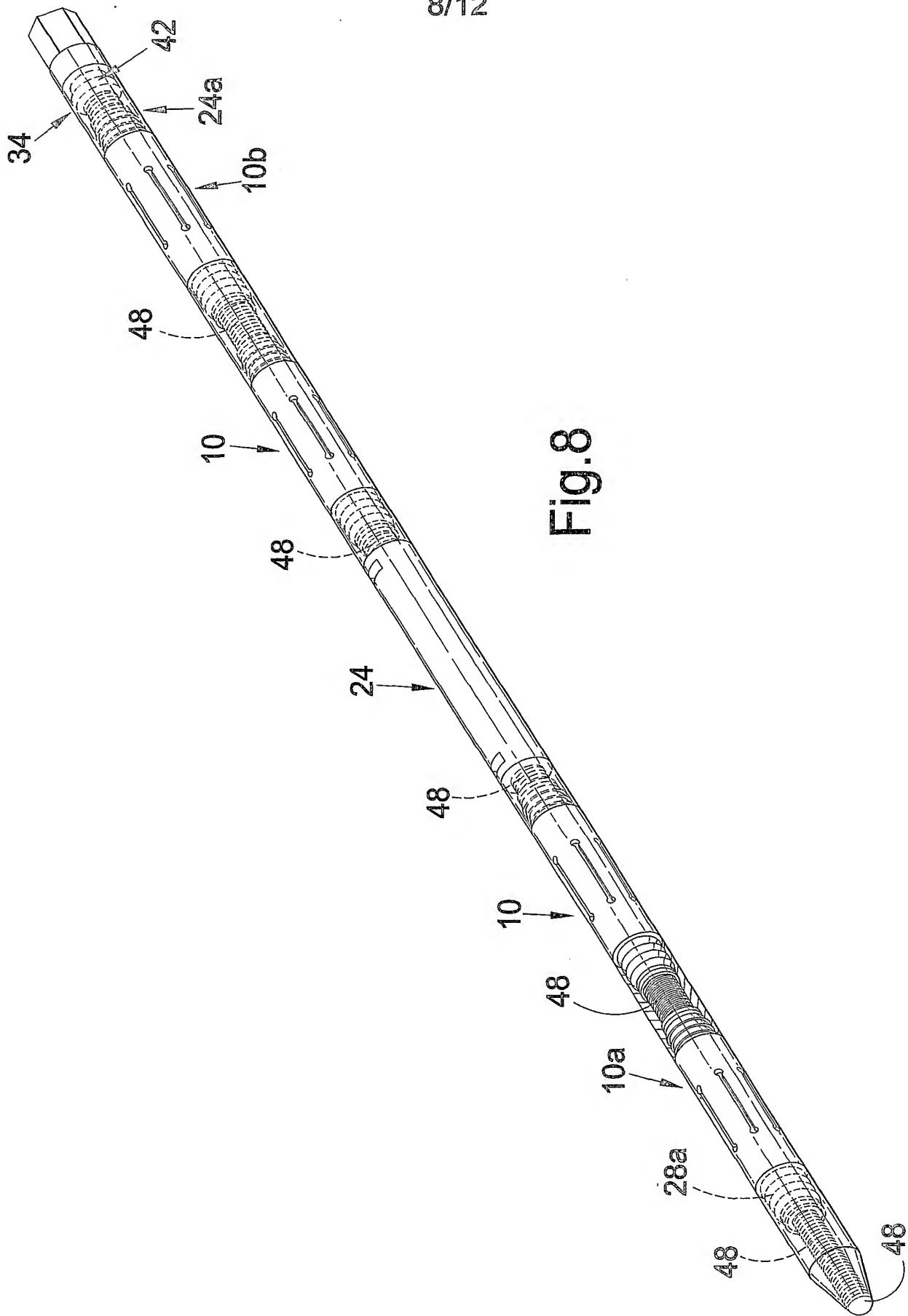


Fig.7b

8/12



9/12

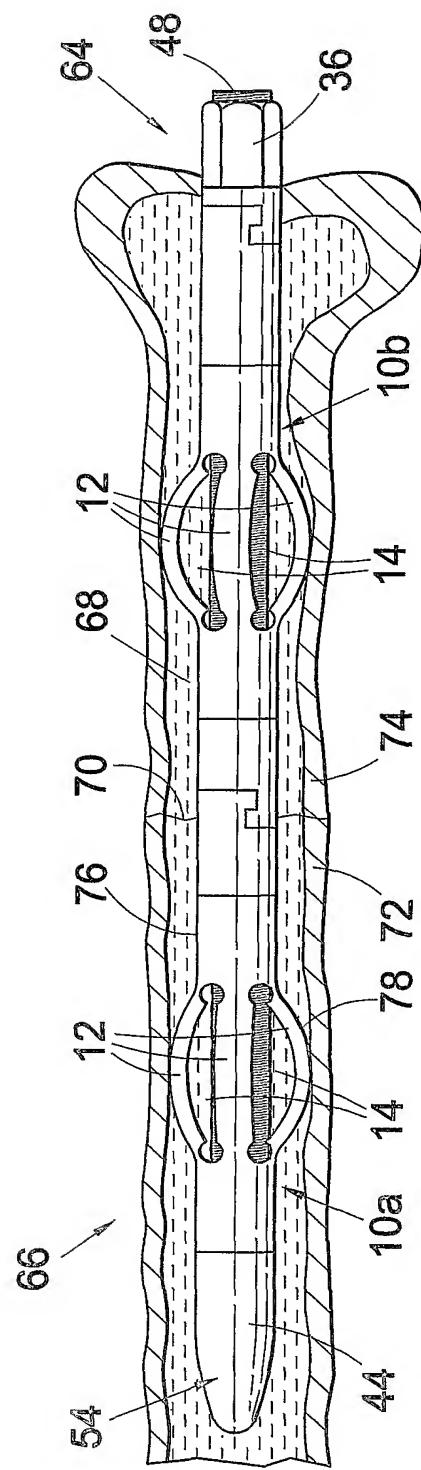


Fig.9

10/12

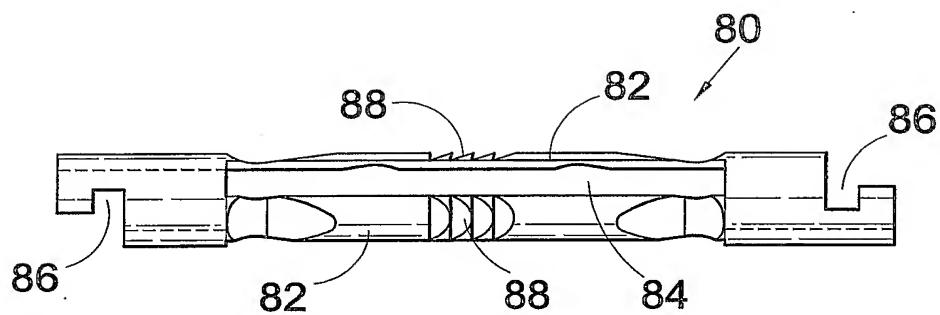


Fig. 10a

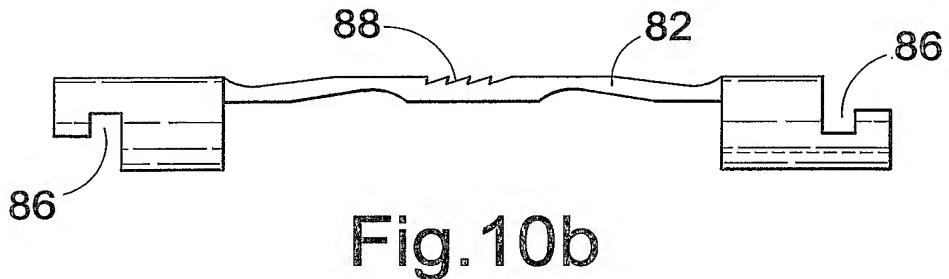


Fig. 10b

11/12

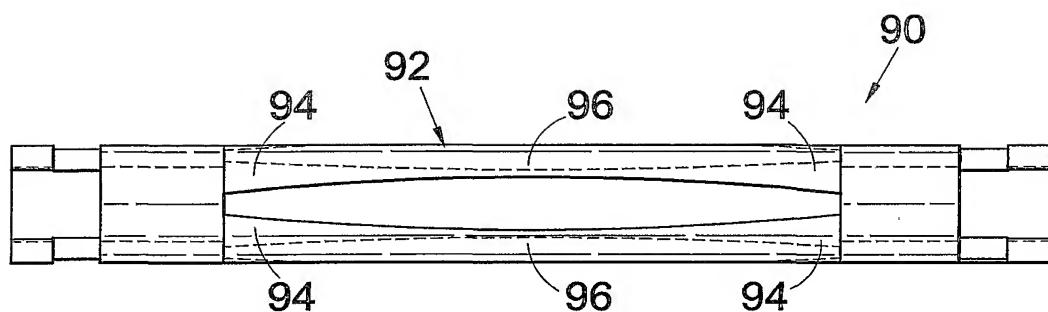


Fig.11a

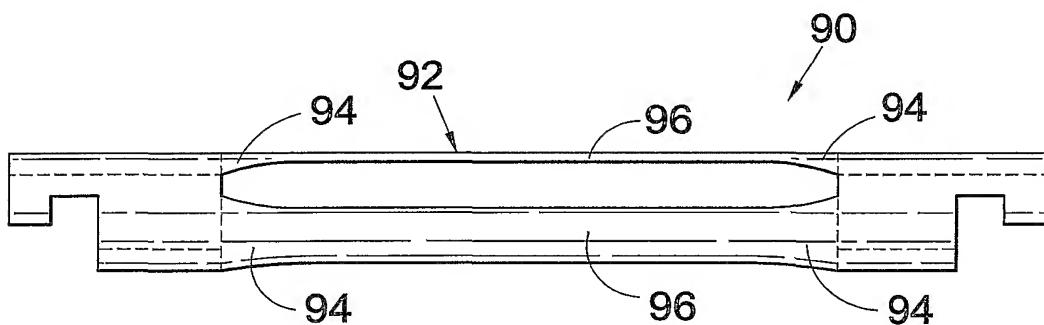


Fig.11b

12/12

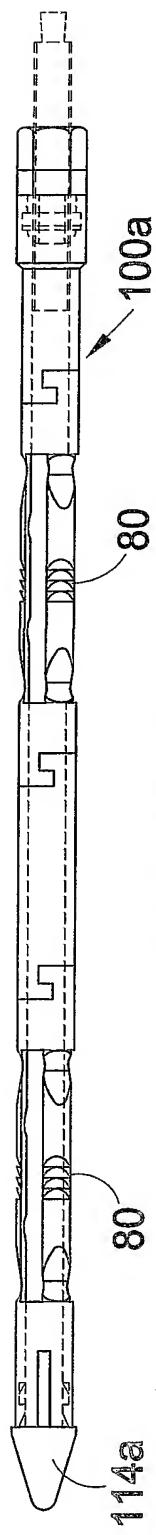


Fig. 12a

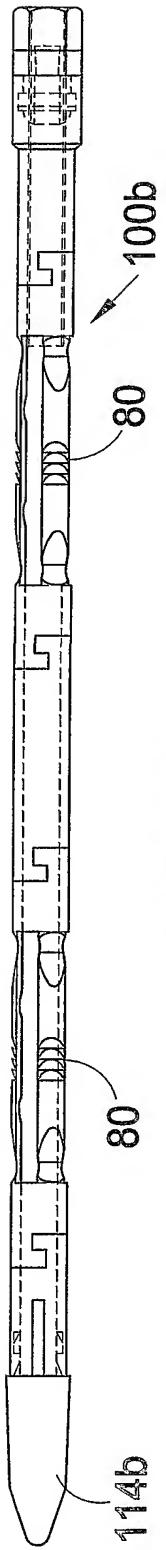


Fig. 12b

INTERNATIONAL SEARCH REPORT

I ational Application No
PCT/GB 02/00311

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/72

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 970 666 A (JOHNSON & JOHNSON MEDICAL LTD) 12 January 2000 (2000-01-12) column 4, line 7 - line 16 column 4, line 24 - line 37 column 5, line 15 - line 25 figures 7,15 ----	1-10, 15-19,27
X	US 3 779 239 A (MULLER J ET AL) 18 December 1973 (1973-12-18) column 4, line 17 - line 26 column 4, line 45 - line 65 figure 1 ----	1-8, 10-13,28 14
Y	US 4 492 226 A (DAVYDOV ANATOLY B ET AL) 8 January 1985 (1985-01-08) column 3, line 14 - line 18 figure 1 ----	1-8,28
X		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

24 April 2002

Date of mailing of the international search report

10/05/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Storer, J

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 02/00311

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 741 256 A (ADVANCED TECHNICAL FABRICATION) 23 May 1997 (1997-05-23) page 5, line 16 -page 6, line 27	10,20, 21,24
A	page 7, line 22 - line 28 page 8, line 4 - line 9 figures 1-7 ----	1-5,7,8, 28
Y	DE 198 35 096 A (LOB HELKE)	14
A	27 January 2000 (2000-01-27) abstract -----	1-9, 15-18

INTERNATIONAL SEARCH REPORT

International Application No. PCT/GB 02 00311

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 29,30

Claims 29 and 30 rely, in respect of their technical features, on references to the drawings. Not only does this contravene Rule 6.2(a) PCT, but a lack of clarity within the meaning of Article 6 PCT also arises, since the claims relate to a great many possible permutations. In view of this lack of clarity, no meaningful search of these claims is possible. Consequently, the search has been carried out for those parts of the application which do appear to be sufficiently clear, namely the subject-matter of claims 1-28.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 02/00311

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
EP 0970666	A	12-01-2000	EP 0970666 A2 JP 2000051250 A US 6200349 B1	12-01-2000 22-02-2000 13-03-2001
US 3779239	A	18-12-1973	DE 2112139 A1 BE 780356 A1 CH 530202 A CS 179377 B2 FR 2130131 A5 GB 1375293 A IT 953474 B JP 51017359 B SE 371573 B SU 419004 A3	28-09-1972 03-07-1972 15-11-1972 31-10-1977 03-11-1972 27-11-1974 10-08-1973 01-06-1976 25-11-1974 05-03-1974
US 4492226	A	08-01-1985	CA 1149105 A1 DE 2945628 A1 FR 2467584 A1 JP 1191260 C JP 56063347 A JP 58020628 B JP 1341940 C JP 56083337 A JP 61006661 B	05-07-1983 21-05-1981 30-04-1981 29-02-1984 29-05-1981 23-04-1983 14-10-1986 07-07-1981 28-02-1986
FR 2741256	A	23-05-1997	FR 2741256 A1 AU 7698396 A WO 9718769 A1	23-05-1997 11-06-1997 29-05-1997
DE 19835096	A	27-01-2000	DE 19835096 A1 AU 5370799 A WO 0006037 A1 EP 1098600 A1	27-01-2000 21-02-2000 10-02-2000 16-05-2001